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September 22, 2022

VIA CM/ECF
Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Pursuant to the Court's request during the September 8, 2022 hearing and its subsequent order (ECF 2157), please accept this letter on behalf of Plaintiffs in opposition to ZHP's proposed redactions to Exhibit CC of ECF 1189.

As the Court knows, this is ZHP's third opportunity to justify the sealing of either the entirety of this document or certain portions of it. Each time is essentially a revised motion to seal, but ZHP only provided the requisite declaration in support of its first request to seal the entire document. Loc. R. 5.3(c)(3). It has never provided a more specific declaration in support of sealing certain portions of the document. This may have been oddly understandable given its initial position on "redactions," where it asked for nearly the entire document to remain under seal.

However, after the Court asked Plaintiffs about the specific parts of the document that it thought could warrant sealing and Plaintiffs seemed to address the Court's concerns,[1] ZHP now asks for significantly fewer redactions but also fails to justify them with the requisite specificity. (ECF 1871, ¶ 15 (quoting *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 924 F.3d 662, 672-73 (3d Cir. 2019)) (stating: "To overcome that strong presumption, the District Court must articulate the compelling, countervailing interests to be protected, make specific findings on the record concerning the effects of disclosure, and provide an opportunity for interested third parties to be heard. In delineating the injury to be prevented, specificity is essential. ***Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.*** Careful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants.")); *see also In re Caterpillar Inc., C13 and C15 Engine Prods. Liab. Litig.*, MDL No. 2540, 2015 WL 12830520, at *3 (D.N.J. Jan. 29, 2015) (**denying motion to seal that was supported by an affidavit without personal knowledge**) (ECF 1874-1); *Schatz-Bernstein v. Keystone Food Prods., Inc.*, No. 08–3079–RMB–JS., 2009 WL 1044946, at *2 (D.N.J. Apr. 17, 2009) (same) (ECF 1874-2). These legal principles must be firmly applied.

ZHP's first declaration was "bereft of specific examples or articulated reasoning" justifying the sealing of this document in its entirety, (ECF 1873-3, p. 2-3), and ZHP has not even provided a legal brief explaining why its new redactions are proper. *Avandia*, 924 F.3d at 673. The Court should note that these requirements are not mere formalities, as ZHP bears the burden on its motion

[1] ZHP does not seek to seal the parts of the document that the Court asked Plaintiffs about potentially keeping under seal. (9/18/2022 Tr. 16:13-17:3, 18:19-22 (stating, **"I went through this," and "[r]eally the only thing I came up with was the information starting at ZHP 02324779 and going over to 4787," so "I thought everything else could be produced"**).

to seal, and Plaintiffs cannot reasonably be expected to respond to broad conclusory allegations, let alone the vacuum left by ZHP with respect to its updated redactions. (ZHP's current proposed redactions are attached hereto as Ex. 1). As a result, Plaintiffs ask the Court to enter an order confirming that Ex. CC is unsealed in its entirety.

Nevertheless, Plaintiffs will briefly explain why ZHP's proposed redactions are not justified. To that end, it is important to remember that **"the more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access."** *Avandia*, 924 F.3d at 670 (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)).

> The common law right of access "antedates the Constitution." *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. **The right of access "promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court."** *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access "diminishes possibilities for injustice, incompetence, perjury, and fraud." *Id.* Moreover, "the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness." *Id.*
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> **[T]he public's right of access must be the starting point, not just one of multiple factors.** The scale is tipped at the outset in favor of access. And **the right of access is not a mere formality**—it "promotes public confidence in the judicial system"; "diminishes possibilities for injustice, incompetence, perjury, and fraud"; and "provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness." *Littlejohn*, 851 F.2d at 678. **These interests are particularly important in a**

> **case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.**

Avandia, 924 F.3d at 672, 677 (emphasis added). Importantly, the Third Circuit has "repeatedly said that **concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access**." *Id.* at 676 (emphasis added) (collecting cases).

On remand from the Third Circuit in *Avandia*, the trial court unsealed "55 documents—including clinical studies, GSK submissions to the FDA, internal GSK emails and letters, records of teleconferences between GSK and the FDA, Avandia presentations and plans, and some court filings in the MDL," with the exception of "certain personal information that Plaintiffs do not object to redacting." *In re Avandia Mktg, Sales Practices and Prods. Liab. Litig.*, 484 F. Supp. 3d 249, 264-68 (E.D. Pa. 2020) (emphasis added). The court summarized its decision in the following manner:

> Justice Brandeis famously declared that "sunlight is the most powerful of all disinfectants." **Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents.** Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.

Id. at 268 (emphasis added).

Third Circuit precedent requires the denial of ZHP's request for redactions to ECF 1189, Ex. CC. ZHP asks for the Court to redact the names of inspectors and other government officials

on ZHP02324736, but ZHP's sole declaration does not support such redactions, even accepting its broad and conclusory allegations of "competitive harm." (EFC 1873-3, p. 2-3). As government officials, these people are publicly known as working in these roles for the entities in question. *See, e.g.*, https://www.pharmtech.com/authors/cristina-baccarelli?page=NaN (stating, "Cristina Baccarelli is a GMP inspector of the Italian Medicines Agency"). Given the public right of access, the Court should unseal this information. *Avandia*, 924 F.3d at 670, 672, 677.

ZHP's next set of redactions concerns the development, quality control, and discovery of NDMA in its valsartan manufacturing processes. Crucially, **"concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access."** *Avandia*, 924 F.3d at 676 (emphasis added) (collecting cases). On ZHP02324741, ZHP seeks to conceal deficiencies in its risk assessment of the NDMA contamination after its "discovery" in mid-2018. This wrongdoing is not proprietary, as these defects are identified by the EMA, and the observations concern the use of widely use materials in the manufacture of valsartan. *See* Baertschi & Olsen, *Mutagenic Impurities, 12.8 Case study 3—N-Nitrosamines in sartans*, in *Specification of Drug Substances and Products* (2d Ed. 2020) https://www.sciencedirect.com/topics/chemistry/valsartan (stating, "In a similar way, triethylamine, which has been used in some valsartan manufacturing processes, can also degrade to form diethylamine, which can be N-nitrosylated to form NDEA"). Defendants have even publicly filed Plaintiffs' expert Dr. Stephen S. Hecht's entire report, discussing how one of ZHP's valsartan manufacturing processes created NDEA due to its use of triethylamine with sodium nitrite quenching. (ECF 1714-3, p. 21). The Court should therefore deny ZHP's requested redactions on ZHP02324741.

On ZHP02324742, ZHP asks the Court to keep a list of its customers sealed. Not surprisingly, as in the United States, when ZHP had to recall its contaminated valsartan, its customers in Europe had to do the same, and those recall lists are obviously public. *See Recall of drugs containing the active ingredient valsartan from the Chinese manufacturer Zhejiang Huahai Pharmaceutical* (May 7, 2018), https://www.basg.gv.at/en/market-surveillance/official-announcements/detail/recall-of-drugs-containing-the-active-ingredient-valsartan-from-the-chinese-manufacturer-zhejiang-huahai-pharmaceutical (listing G.L. Pharma and Genericon Pharma as recalling valsartan containing ZHP API). The public also has a heightened interest in which companies purchased ZHP's contaminated ZHP (even in the United States, many people either travel to Europe or live there temporarily while maintaining their citizenship). The Court should therefore deny ZHP's motion to seal this information.

ZHP also asks the Court to seal the conversion rate of the TEA manufacturing process and some of the chemicals use in ZnCl2 manufacturing process, both of which contaminated ZHP's valsartan API with nitrosamines. (*See* ZHP02324743). It is public information that ZHP implemented the TEA manufacturing process due to its "low conversion rate" in comparison to the ZnCl2 process. In Jun Du's words, "the cost reduction was so significant it is what made it possible for the firm to dominate the world market share." (ECF 1907-1, p. 25). The public has a heightened interest in understanding what ZHP considered a sufficiently "low conversion rate" to justify developing the alternative manufacturing process that would result in the NDMA levels in all of its finished dose valsartan. Moreover, it is public knowledge that ZnCl2 process used ZnCl2 and DMF. *See* ZHP's Patent for Improved Method For Preparing Tetrazole For Valsartan (2014) (acknowledging its use of dimethylformamide (DMF) and sodium nitrite quenching in its

manufacture of valsartan), https://patents.google.com/patent/CN104045602A/en. The Court should therefore deny ZHP's request to redact this information.

On the next four pages (ZHP02324744-47), ZHP seeks to redact the name of the company that "discovered" NDMA in its valsartan, the lab that company hired to confirm its presence, and the name of a customer that submitted complaints regarding unknown peaks in its valsartan as early as 2014. ZHP cannot claim that what other companies independently did to discover the nitrosamine contamination is somehow so proprietary to ZHP that ZHP would be harmed by disclosure. Again, Dr. Hecht's report, filed on the public docket by Defendants, states that Novartis discovered the contamination and contracted a lab to further confirm it was NDMA. (ECF 1714-3, p. 20). ZHP's declaration supporting the sealing of this document does not explain how the identity of the lab Novartis hired to confirm ZHP's valsartan was contaminated with NDMA would cause it any type of harm, and Plaintiffs are unable to contemplate such a harm to attempt to refute. If anything, the disclosure of this fact would help that lab's business, as it is clearly capable of adequately analyzing drugs for genotoxic contaminants such as NDMA. The same argument applies to the other customer discussed on ZHP02324745-46, where that customer complained about unknown peaks as early October 2014. The Court should decline to seal this information.

From ZHP02324748 to -48, ZHP then repeats its request to redact publicly available information concerning its defective and defunct manufacturing processes for valsartan. (*See, e.g.,* ECF 1714-3, p. 6, 20-23 (stating, **"The nitrosation of secondary amines occurs so easily that it was once widely used in qualitative organic analysis as a test for the presence of a secondary amine, but after the discovery of nitrosamine carcinogenesis, this was eventually discontinued"**)). ZHP's declaration does not explain how redacting this information is necessary to protect it from anything besides the reputational harm of the public knowing how its valsartan

supply became needlessly contaminated with a carcinogen. That is not a basis for sealing this information. *Avandia*, 924 F.3d at 670, 672, 677. The Court should deny ZHP's request to do so.

ZHP asks the Court to redact a general description of its updated valsartan manufacturing process on ZHP02324750, but that process is patented and that patent states, "The inventors of the present application have further researched the synthesis process of valsartan and found that, **before quenching the azide, the valsartan methyl ester intermediate is separated, which can avoid the high Possibility that impurities such as toxic N-nitrosodimethylamine (NDMA),** valsartan impurity K and valsartan N-chloride are brought into the valsartan bulk drug; further, by optimizing other operating conditions, For example, controlling the water content in the solvent, the crystallization temperature, etc. during crystallization, to prepare a high-purity (without the above-mentioned impurities) valsartan product; the present invention is completed based on the above-mentioned findings." WO2020010643 - METHOD FOR SYNTHESIZING VALSARTAN, https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2020010643 (A Google translation of the full text is attached hereto as Ex. 2, with the multilingual abstract attached as Ex. 3).[2] **A cursory review of this incredibly detailed public patent shows that there is no need for the redaction of the terms ZHP seeks to keep under seal.**

ZHP also asks the Court to redact details concerning the potential contamination of its losartan and irbesartan on ZHP02324750. Importantly, it is public knowledge that ZHP's losartan and irbesartan were contaminated with NDEA. *See* FDA's Recall Announcement Regarding

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[2] Notably, ZHP's abstract contains its own English translation and states "**The synthesization method provided in the present invention can avoid from the process source the possibility that *highly toxic impurities such as N-nitrosodimethylamine (NDMA)***, a valsartan impurity K, and valsartan N-chloride generated in the azide quenching process are introduced into the valsartan methyl ester intermediate, and are further introduced into the valsartan active ingredient, thereby ensuring the valsartan medication safety." *Id.* (Ex. 3).

ZHP's Losartan, https://tinyurl.com/jbpwxrk; FDA's Recall Announcement Regarding ZHP's Irbesartan, https://tinyurl.com/3eanb2sf. Moreover, the public has a heightened interest in understanding the cause of this contamination, especially in light of its prior inadequate risk assessments. As ZHP's July 27, 2017 email—which ZHP always proclaims is really about irbesartan—states, "This is a common problem in the production and synthesis of sartan APIs." (Ex. 4 hereto). And Dr. Hecht's report clearly explains how "NDEA form[ed] when 3 factors were present: 1) trimethylamine used as a catalyst for tetrazole formation; 2) nitrite used for decomposition of excess sodium azide; and 3) both factors 1 and 2 are together with the crude product." (ECF 1714-3, p. 21). The previously quoted article also states:

> The nitrosamine impurities were formed during synthesis of the drug substance when the synthetic route was changed and a reactive reagent used in the formation of the **tetrazole** moiety (sodium azide) was removed using **sodium nitrite** during the work-up; under acidic conditions nitrite can form nitrous acid, a strong nitrosylating reagent. Apparently, impurities in the solvent **DMF** (dimethylamine and diethylamine) were N-nitrosylated during the work-up, resulting in the formation of NDMA, which was not seen in the innovator product. In a similar way, **triethylamine**, which has been used in some valsartan manufacturing processes, can also degrade to form diethylamine, which can be N-nitrosylated to form NDEA. **N-nitroso compounds belong to the "cohort of concern" because they can display extremely high carcinogenic potency.**

Baertschi & Olsen, *Mutagenic Impurities, 12.8 Case study 3—N-Nitrosamines in sartans*, in *Specification of Drug Substances and Products* (2d Ed. 2020) (emphasis added), https://www.sciencedirect.com/topics/chemistry/valsartan. The Court should deny ZHP's request to seal similar information regarding ZHP's losartan and irbesartan.

On ZHP02324751 to -53, ZHP again asks the Court to redact the basic ideas found in the public patent for its updated valsartan manufacturing process. *See* WO2020010643, https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2020010643 (stating, "The inventors

of the present application have further researched the synthesis process of valsartan and found that, **before quenching the azide, the valsartan methyl ester intermediate is separated, which can avoid the high Possibility that impurities such as toxic N-nitrosodimethylamine (NDMA),** valsartan impurity K and valsartan N-chloride are brought into the valsartan bulk drug; further, by optimizing other operating conditions, For example, controlling the water content in the solvent, the crystallization temperature, etc. during crystallization, to prepare a high-purity (without the above-mentioned impurities) valsartan product; the present invention is completed based on the above-mentioned findings") (Exs. 2 and 3 hereto). On the bottom of ZHP02324753, ZHP seeks to redact the limit for NDMA, which is obviously public in both the United States and European Union. *See* FDA, *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry*, p. 10 (Feb. 2021), https://www.fda.gov/media/141720/download (limiting NDMA to 96 ng or 0.3 ppm); EMA, *Nitrosamine impurities in human medicinal products*, p. 78 (June 25, 2020) (limiting NDMA to 96 ng or 0.3 ppm), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf. ZHP's declaration does not support the remaining redactions with the requisite specificity, especially in light of the detailed information contained in its public patent and the public's right to access this information. *See Avandia*, 924 F.3d at 670, 672, 677. The Court should not redact this information from the report.

From ZHP02324756 to -64, ZHP seeks to redact the EMA's critiques of its improper SOPs and testing methods, as well as other violations of current good manufacturing processes (cGMP). The public has a heightened interest in ZHP's cGMP violations, and the FDA has published the proper way to test drugs like valsartan, losartan, and irbesartan for nitrosamine impurities. FDA, *Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS) Method for the Determination of Six Nitrosamine Impurities in ARB Drugs* (May 21, 2019),

https://www.fda.gov/media/125478/download; *see also* ECF 1714-3, p. 21 (discussing "In the specific investigation here, a peak eluting after the solvent toluene was ultimately definitively identified by an outside laboratory, using combined gas chromatography-mass spectrometry (GC-MS), as NDMA"). Furthermore, a "**concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access**." *Avandia*, 924 F.3d at 676 (emphasis added) (collecting cases). The Court should deny ZHP's request to redact this information.

ZHP's final set of designations from ZHP02324770 to -77 overlap with its earlier requests in part and are unjustified for the reasons already explained. Plaintiffs note that these pages contain a summary of the EMA's nine major deficiencies and eight "other" deficiencies. The public has a heightened interest in this summary information. ZHP's declaration in support of sealing it is "bereft of [the requisite] specific examples or articulated reasoning," and shielding ZHP from reputational harm does not justify ZHP's request. *Avandia*, 924 F.3d at 673, 676. There is no articulated declaration as to how harm is likely to occur once unsealed. The Court should consequently decline to order these redactions.

In sum, ZHP has not provided the Court with a declaration based on personal knowledge with enough specificity to justify its requested redactions, let alone overcome the public's right to access court records **"in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug."** *Avandia*, 924 F.3d at 672, 677 (emphasis added). ZHP's "**concern about [its] public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access**." *Id.* at 676 (emphasis added) (collecting cases). And nearly all of the redactions concern public information or commonsense

inferences from such information. Therefore, the Court should unseal Exhibit CC to ECF 1189 in its entirety.

Thank you for your courtesies and consideration.

Respectfully,

ADAM M. SLATER

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cc: All Counsel (via CM/ECF)